

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 71301-74702	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/SE2004/000451	International filing date (day/month/year) 24.03.2004	Priority date (day/month/year) 24.03.2003
International Patent Classification (IPC) or national classification and IPC A61K 39/39, A61K 39/00		
Applicant Isconova AB et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
 - a. ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

Date of submission of the demand 18.10.2004	Date of completion of this report 04.07.2005
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. +46 8 667 72 88 Form PCT/IPEA/409 (cover sheet) (April 2005)	Authorized officer Malin Söderman/ELY Telephone No. +46 8 782 25 00

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE2004/000451

Box No. I Basis of the report

1. With regard to the language, this report is based on:

- ☐ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rules 12.3(a) and 23.1(b))
- ☐ publication of the international application (Rule 12.4(a))
- ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ the international application as originally filed/furnished
- ☐ the description:
- pages _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the claims:
- pages _____ as originally filed/furnished
- pages* _____ as amended (together with any statement) under Article 19
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the drawings:
- pages _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>1-17</u>	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	<u>1-17</u>	NO
Industrial applicability (IA)	Claims	<u>1-17</u>	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The following document is cited in this opinion:

1. (D1) Iosef C, et al. Systemic and intestinal antibody secreting cell responses and protection in gnotobiotic pigs immunized orally with attenuated Wa human rotavirus and Wa 2/6-rotavirus-like-particles associated with immuno-stimulating complexes. Vaccine. 2002 Mar 15;20(13-14):1741-53.

The present application relates to the use of immune stimulating complex (iscom) particles as adjuvant for an antigenic composition, which comprises live micro-organisms.

D1, which is considered to be the most relevant prior art, discloses the use of iscom particles in combination with live micro-organisms (attenuated human rotavirus (attHRV)) as a vaccine strategy (see specially page 1742, col. 1, lines 41-46 and page 1752, col. 1, lines 7-9).

The technical difference in terms of claimed technical features between the present application and D1 is that in the claimed invention the iscom particles administered are in the same composition as the live micro-organisms, whereas in D1 these are administered separately. It has not been shown that this technical difference shows any technical effect in comparison with what is already known (D1).

The problem to be solved is, therefore, to develop an alternative way to administer iscom particles in combination with live micro-organisms.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: BOX V

To develop this kind of alternative administration method is considered to be obvious for a person skilled in the art, since it is well known in the art that an adjuvant and the antigen can be administered together. Further, no surprising technical effect has been shown and the application and D1 belong to the same technical field.

Consequently, according to the motivation above, the subject matter claimed in claims 1-17 is considered to lack an inventive step.